DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Centinel Spine, Incorporated
% Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H. Street Northwest, 12th
Washington, District of Columbia 20005

November 7, 2014

Re: K141942
Trade/Device Name: MIDLINE II™ / MIDLINE II-Ti™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: October 8, 2014
Received: October 9, 2014

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141942

Device Name

MIDLINE II™ / MIDLINE II-Ti™

Indications for Use *(Describe)*

The MIDLINE II™ / MIDLINE II -Ti™ is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The MIDLINE II™ / MIDLINE II -Ti™ is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

The MIDLINE II™ / MIDLINE II -Ti™ system must be used with bone grafting material (autograft only).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Device Trade Name: MIDLINE II™ / MIDLINE II-Ti™

Manufacturer:
Centinel Spine, Inc.
900 Airport Road, Suite 3B
West Chester, PA 19380

Contact:
Mr. John Parry
Development Manager
Phone: (484) 887.8813
J.Parry@centinelspine.com

Prepared by:
Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
Fax: (202) 552-5798

Date Prepared: October 8, 2014

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: OVD

Primary Predicate: K133286 (MIDLINE™)

Additional Predicates: STALIF MIDLINE™ (K101301), Aesculap SIBD XP Spinal System (K111122), SpineSmith Cynch Spinal System (K102090), NuVasive Brigade Hyperlodotic System (K123045), Theken Spine VuaPOD (K101310)

Reference Device: K133200 (STALIF C® Ti)

Indications For Use:
The MIDLINE II™ / MIDLINE II-Ti™ is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the

treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The MIDLINE II™ / MIDLINE II-Ti™ is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

The MIDLINE II™ / MIDLINE II-Ti™ system must be used with bone grafting material (autograft only).

Device Description:
The MIDLINE II™ / MIDLINE II-Ti™ is a radiolucent intervertebral body fusion device manufactured from either PEEK-OPTIMA® LT1 supplied by Invibio or Zeniva ZA PEEK supplied by Solvay per ASTM F2026 with three metallic X-ray markers manufactured from unalloyed Tantalum (ASTM F560) and plasma sprayed with optional commercially pure titanium (CPTi) per ASTM F1580. The device is secured with titanium (Ti-6Al-4V per ASTM F136) unicortical cancellous bone screws provided and is intended to be used without supplemental fixation. The purpose of this 510(k) is to modify the MIDLINE™ (K133286) to include a titanium coating (ASTM F1580-12) and an additional lordotic option.

The MIDLINE II™ / MIDLINE II-Ti™ is provided in 11-21mm heights, 30-42mm widths, 24-30.2mm lengths, and lordotic angles ranging from 8°-20°. The devices are provided sterile.

Predicate Device:
The subject MIDLINE II™ / MIDLINE II-Ti™ device is substantially equivalent to predicate MIDLINE™ and STALIF MIDLINE™ devices (K133286, K101301) with respect to indications, design, function, and performance.

Substantial Equivalence:
Testing performed indicate that the MIDLINE II™ / MIDLINE II-Ti™ is as mechanically sound as predicate devices. Testing included static compression, static torsion, static compression-shear, dynamic compression, dynamic torsion, dynamic compression-shear, expulsion, and subsidence per ASTM F2077-11 and F2267-04. In addition, coating validation testing was performed, including static tensile bonding, shear bonding, and Taber abrasion testing. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Conclusion:
Centinel Spine provided sufficient information to demonstrate the MIDLINE II™ / MIDLINE II-Ti™ is substantially equivalent to predicate MIDLINE™ and STALIF MIDLINE™ devices (K133286, K101301).